Claims

1. A slow release formulation comprising one or more biologically active molecules from a solid composition prepared by exposure of the biologically active molecules to an organic solvent under conditions wherein a precipitate, lyophilate or crystal is formed.

2. A slow release formulation comprising precipitate, lyophilate or crystals of a polypeptide prepared by exposure of the polypeptide to an organic solvent, which polypeptide is released from the formulation in aqueous solution for a period of at least 7 days.

3. A formulation comprising precipitate, lyophilate or crystals of a biologically active polypeptide prepared by exposure of the polypeptide to a polar protic organic solvent, which formulation, when administered to a patient, releases said polypeptide at a rate providing an average steady state dosage of at least the ED_{50} for the polypeptide for a period of at least 7 days.

4. The formulation of any of claims 1-3, wherein the organic solvent is an alcohol, an aldehyde, a ketone, a hydrocarbon, an aromatic hydrocarbon, or a mixture thereof.

5. The formulation of any of claims 1-3, wherein the organic solvent is an alcohol or mix of alcohols.

6. The formulation of claim 5, wherein the alcohol is a lower alcohol, or mixture thereof.

7. The formulation of claim 5, wherein the alcohol is selected from the group consisting of methanol, ethanol, isopropanol, n-propanol, n-butanol, isobutanol, and t-butanol, or a mixture thereof.

8. The formulation of any of claims 1-3, wherein the organic solvent is a polar protic solvent.

9. The formulation of any of claims 1-3, wherein the organic solvent is a water-miscible polar protic solvent.

10. The formulation of any of claims 1-3, wherein the biologically active molecules or polypeptides are released from the formulation in aqueous solution at a rate which provides an average steady state dosage of at least the ED_{50} for the biologically active molecules or polypeptides for a period of at least 50 days.

11. The formulation of any of claims 1-3, wherein the organic solvent(s) are chosen such that, when administered to a patient, the solvent released from the formulation at a rate which

remains at least one order of magnitude below the IC_{50} for deleterious side effects, if any, of the solvent.

12. The formulation of claim 1, wherein biologically active molecule is a polymer selected from the group consisting of a protein, a peptide, a nucleic acid, an oligonucelotide, a carbohydrate, a ganglioside, or a glycan.

13. The formulation of any of claims 2-3, wherein the polypeptide is selected from the group consisting of cytokines, growth factors, somatotropin, growth hormones, colony stimulating factors, , erythropoietin, plasminogen activators, enzymes, T-cell receptors, surface membrane proteins, lipoproteins, clotting factors, anticlotting factors, tumor necrosis factors, transport proteins, homing receptors, and addressins.

14. The formulation of claim 13, wherein the polypeptide is selected from the group consisting of rennin; human growth hormone; bovine growth hormone; growth hormone releasing factor; parathyroid hormone; thyroid stimulating hormone; lipoproteins; α-1-antitrypsin; insulin; proinsulin; follicle stimulating hormone; calcitonin; luteinizing hormone; glucagon; a clotting factor such as factor VIIIC, factor IX, tissue factor, and von Willebrands factor; anti-clotting factors; atrial natriuretic factor; lung surfactant; a plasminogen activator; bombesin; thrombin; hemopoietic growth factor; tumor necrosis factor-α; tumor necrosis factor-β; enkephalinase; RANTES (regulated on activation normally T-cell expressed and secreted); human macrophage inflammatory protein (MIP-1-α); a serum albumin; mullerian-inhibiting substance; relaxin A-chain; relaxin B-chain; prorelaxin; gonadotropin-associated peptide; a microbial protein; DNase; inhibin; activin; vascular endothelial growth factor (VEGF); receptors for hormones or growth factors; integrin; protein A; protein D; rheumatoid factors; a neurotrophic factor; platelet-derived growth factor (PDGF); a fibroblast growth factor; epidermal growth factor (EGF); transforming growth factors (TGF); insulin-like growth factor-I; insulin-like growth factor-II; des(1-3)-IGF-I (brain IGF-I); insulin-like growth factor binding proteins; CD proteins; erythropoietin; osteoinductive factors; immunotoxins;; an interferon; colony stimulating factors (CSFs); interleukins (ILs); superoxide dismutase; T-cell receptors; surface membrane proteins; decay accelerating factor; antigens; transport proteins; homing receptors; addressins; regulatory proteins; immunoglobulin-like proteins; antibodies; and nucleases, or fragments thereof.

15. The formulation of claim 1, wherein biologically active molecule is selected from the group consisting of a lipid and a sterol.

16. The formulation of claim 1, wherein biologically active molecule is a small organic compound.

17. The formulation of any of claims 1-3, which is a precipitate.

18. The formulation of any of claims 1-3, which is a lyophilate.

19. A formulation comprising a precipitate or lyophilate of a polypeptide, which precipitate or lyophilate includes at least 50 percent (molar) polar protic organic solvent(s), and which formulation, when administered to a patient, releases said polypeptide at a rate providing an average steady state dosage of at least the ED_{50} for the polypeptide for a period of at least 7 days.

20. A medicament for administeration to an animal, comprising the formulation of any of claims 1-3.

21. The medicament of claim 20, for administeration to a mammal.

22. The medicament of claim 20, for administeration to a human.

23. A method for manufacturing a medicament comprising formulating the formulation of any of claims 1-3 with a pharmaceutically acceptable excipient.

24. A method method for manufacturing a slow release formulation of a biologically active molecule, comprising (a) exposing said biologically active molecules to an organic solvent, and (b) forming a precipitate, lyophilate or crystal.

25. A method for conducting a pharmaceutical business comprising:

(a) preparing a formulation of any of claims 1-3;

(b) providing marketing and/or product literature for instructing healthcare providers on the use of said formulations; and

(c) providing a distribution network for deliverying said formuation to healthcare providers.